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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,013	10/07/2003	Lawrence M. Kauvar	388512010900	6212

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,013

Applicant(s)

KAUVAR ET AL

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 10, 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges Applicants' reply filed January 10, 2005, said reply amending claims 1 and 3, and canceling claim 9.

Currently, claims 1-8 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, claim 3 has been amended to add the limitation of "a multiplicity of detection spaces." Such a limitation does not appear to be disclosed in Applicants' specification, as originally filed, and thus constitutes new matter.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, the recitation of the term "hue" is indefinite because a person of ordinary skill in the art cannot ascertain what physical parameters comprise "hue", or how to accurately quantitate "hue", or whether "hue" comprises a qualitative visual assessment. The term "wavelength" is a suggested alternative to the term "hue."

In claim 3, the recitation of "pattern" is indefinite because it is not clear what object or property forms the basis or bases of said "pattern." It is not clear how the step of "assessing the number and hue of any particulate label" is related to "obtaining a pattern." In addition, the recitation of "and having a multiplicity of detection spaces" appears grammatically awkward and is indefinite because it is not clear what object(s) has "a multiplicity of detection spaces."

In claim 8, it is not clear what type of "detection space" has a diameter of 400-750 nm.

Claim Rejections - 35 USC § 102

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nie et al. (US 2003/0148544).

Nie et al. describes a composition comprising a multiplicity of different labels, wherein each different label comprises a particulate support to which is coupled one or more first signal-generating moieties which generate a visible hue that characterizes said label (see Fig. 1), a second signal generating moiety which emits the same wavelength at the same intensity from all said different labels (see para. [0069], "all quantum dot system can be synthesized wherein a single QD is used as the analyte signal", "The intensity of the signal generated by the tag attached to the target molecule will be in direct proportion to the amount of target present in the sample"), wherein the wavelength of the signal generated by said second signal-generating moiety is different from the hue which characterizes the label (see para. [0069], "it [analyte signal] can be any wavelength as long as it does not overlap with the coding signal"), and

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wherein said labels further contain reagents which permit each of them to interact specifically with a desired target (see Fig. 1).

With respect to claim 2, Nie et al. describes a composition comprising a multiplicity of different labels, wherein said characterizing signal generating moieties comprise at least two different signal generating entities wherein each of the entities generates a signal different from that generated by the other entity(s) and wherein the resulting hue of the labels resulting from said signal is varied among the different labels whereby each different label is thereby characterized by a different hue (see Fig. 1).

With respect to claim 3, Nie et al. describes a method to provide a pattern of target substances which method comprises contacting an environment containing the target substances with the composition of claim 1 and, assessing the number and hue of particulate labels (see Fig. 4a), wherein said number is assessed by measuring the intensity of the signal emitted from the second signal generating moiety in said detection space (see Fig. 5, para. [0069], "The intensity of the signal generated by the tag attached to the target molecule will be in direct proportion to the amount of target present in the sample").

With respect to claim 4, Nie et al. describe a method wherein the environment is displayed on a support suitable for viewing by microscopy (see Fig. 4a).

With respect to claim 7, Nie et al. describe a method wherein said particulate supports have diameters of 20-200 nm (see para. [0039]).

Claim Rejections - 35 USC § 103

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nie et al. (US 2003/0148544) in view of Kauvar et al. (US 2001/0044116).

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Nie et al. describe a method for providing a pattern of target substances as substantially described supra. Nie et al. do not describe a method wherein the environment comprises intracellular environment or neural circuitry.

However, Kauvar et al. disclose a method using microscopy (See Fig. 1) to view intracellular targets (see p. 6, para. (0062), "cell or dendrites") or neural circuitry (See p. 6, para. (0062), "dendrites"). Therefore, it would have been obvious for a person of ordinary skill in the art to combine the method of contacting an environment to view a pattern of particulate labels of Nie et al. with the method of using microscopy to view intracellular targets or neural circuitry of Kauvar et al. to provide a method of viewing a pattern of particulate labels in an intracellular or neural circuitry environment. A skilled artisan would have had a reasonable expectation of success in using the labels of Nie et al. in a method for viewing an intracellular environment because Nie et al. teach that the use of multicolor optical coding using luminescent QDs offers important advantages and applications that are not possible with other types of dyes (see para. [0017]). Nie et al. also teach that by using their labels, particulate beads can be quantified based on the observed number of quantum dots, i.e. intensity multiplexing.

Response to Arguments

In prior Office Action, claims 1-2 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of the term "hue." In response, Applicants recite a portion of paragraph 9 of the specification and argue that the term "hue" is clearly explained in paragraphs 9 and 17 of Applicants' specification. In addition, Applicants argue that Nie et al. (US 2003/0148544) provide clarity for Applicants' usage of term "hue." Applicants' argument has been carefully considered but is not persuasive for the following reasons:

The term "hue" is not clearly defined anywhere in Applicants' specification. Applicants' claimed invention includes two light-emitting species (i.e. a "first signal-generating moiety" species and a "second signal-generating moiety" species). However, Applicants' specification does not explicitly teach which light-

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emitting species contribute to the formation of "hue." For example, it is not clear whether both a "first signal-generating moiety" species and a "second signal-generating moiety" species contribute to the formation of "hue." Alternatively, it is not clear whether the formation of "hue" is limited to the contribution of light emitting from said "first signal-generating moiety" species only. Applicants' specification does not clearly teach which light-emitting species contribute to the formation of "hue." The recited portion of paragraph 9 teaches that "characterizing light emitting moieties" are different in each different label "whereby each different label is thereby characterized by a different hue." Examiner posits that the recited portion of paragraph 9 does not amount to a definition of the term "hue" as it does not clearly define which light-emitting species contribute to the formation of "hue."

Examiner observes that paragraph 17 of Applicants' specification does not recite the term "hue", much less any clarification of its meaning. The teachings of Nie et al. are not dispositive here.

In prior Office Action, claim 3 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the preamble of claim 3 did not correspond to the outcome of the method. Applicants have amended claim 3 to add the recitation of "obtaining a pattern of target substances in the environment" as the final step in the method. The preamble of claim 3, as amended, appears to correspond to the outcome of the method. However, the recitation of "pattern" is indefinite because it is not clear what object or property forms the basis or bases of said "pattern." It is not clear how the step of "assessing the number and hue of any particulate label" is related to "obtaining a pattern." In addition, the recitation of "and having a multiplicity of detection spaces" appears grammatically awkward and is indefinite because it is not clear what object(s) has "a multiplicity of detection spaces."

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In prior Office Action, claim 8 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what type of "detection space" has a diameter of 400-750 nm. Applicants state that the "detection space" can be no smaller than the measured wavelength and argue that the term "detection space" is described in paragraph 13 of the specification. Applicants' argument has been carefully considered but is not persuasive because the specification does not teach what type of instrument means has a "detection space" having a diameter of 400-750 nm. It is not clear whether "detection space" equates to a field diameter or a field of view in a microscopy means, or whether "detection space" equates to a resolving capability of a microscopy means.

In prior Office Action, claims 1-4, 7 and 9 were rejected under 35 U.S.C. 102(e) as being anticipated by Nie et al. (US 2003/0148544). Applicants submit argumentation that appears to be premised on the assumption that Applicants' composition, as claimed, is limited to a composition wherein the "second signal generating moiety" is coupled to "a particulate support" (see e.g. Applicants' Remarks, paragraph bridging pp. 8-9, "the invention employs a 'counter' signal attached to each particle"). Examiner respectfully disagrees with the premise that Applicants' composition, as claimed, is limited to a composition wherein the "second signal generating moiety" is coupled to "a particulate support." Examiner posits that claim 1 can be much more broadly construed to include a composition comprising a "second signal generating moiety" wherein the "second signal generating moiety" may, or may not, be coupled to "a particulate support." Thus, the composition of Nie et al., wherein the "second signal generating moiety" is coupled to a target, sufficiently anticipates Applicants' invention, as claimed.

Conclusion

No claims are allowed.

The prior art made of record, but not relied upon here, is considered pertinent to applicant's disclosure:

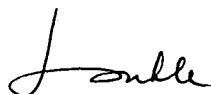
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Schwartz (US 5,093,234) teaches a composition comprising "a second signal generating moiety which emits the same wavelength at the same intensity from all said different labels" (see col. 6, lines 48-52).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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David J Venci
Examiner

03/18/05